

**REMARKS**

Claims 35-55, 74-78, and 101-103 are pending. Withdrawn claims 1-34, 56-73 and 79-100 and previously pending claims 42 and 52 have been canceled without prejudice to their being pursued in any future divisional, continuation or continuation-in-part application. Claims 35, 36, 39-41, 43-45, 47, 49, 50-51, 53-55 and 74 have been amended. The amendments to claims 39-40, 41-45, 47 51 and 53 replace acronyms (e.g. NMWCO) with the acronym's full words. Acronyms have also been replaced in amended claims 35 and 49, which contain additional amendments, described below. Furthermore, claims 35 and 49 have been amended to note that a supernatant is formed by lysing and pelleting the debris. Support for this amendment can be found on page 50 of the specification. Claim 55 has been amended to remove a superfluous reference to the purifying step from within the body of the purifying step (e). No new matter has been entered by these amendments.

**Information Disclosure Statement**

Applicants note the Examiner's statement that the references previously made of record in the parent case are no longer available. Applicants also note that the Examiner has declined to consider the IDS filed on July 22, 2005 due to the unavailability of the references and has requested that applicants submit new copies for consideration by the Examiner.

As agreed in the February 8, 2006 interview, applicants enclose a CD-ROM containing PDF copies of these references. Applicants respectfully request that the Examiner consider these references, initial each reference on the previously submitted IDS and cause them to appear on the face of any patent issuing from this application.

**Rejections under 35 U.S.C. §112**

The Examiner has maintained her rejection of claim 36 under 35 U.S.C. §112 as indefinite over use of the term “synthetic gene” in conjunction with the term “SEQ ID No.” Applicants respectfully traverse the Examiner’s rejection.

Applicants note that the Examiner states that SEQ ID Nos. denote nucleic acid sequences, but not genes per se. Solely to expedite prosecution, applicants have amended claim 36 to replace “synthetic gene” with “polypeptide”. Claim 50 has also been amended in this manner. Support for these amendments can be found, *inter alia*, on page 66 of the specification.

Applicants respectfully maintain that the Examiner’s rejection of claim 36 on §112 grounds is now moot.

The Examiner has also maintained her rejection of claim 50 under 35 U.S.C. §112 as indefinite because it has the phrase “SEQ ID Nos 1-4”. Applicants respectfully traverse the Examiner’s rejection.

Solely to speed prosecution, applicants have amended claim 50 to recite “Seq. ID No. 11” in order to refer to the amino acid sequence of rhUG. Claim 36 has also been amended in this manner. Support for these amendments can be found, *inter alia*, on page 66 of the specification.

Applicants respectfully maintain that the Examiner’s rejection of claim 50 on §112 grounds is now moot.

Additionally, the Examiner has maintained her rejection of dependent claims 74-78 under 35 U.S.C. §112 as indefinite because claim 35, from which they directly or indirectly depend, lacks a step that mentions “intermediates”.

Applicants note that the samples taken at each step are the intermediates, as is commonly understood in the art. However, as agreed to during the interview and solely to speed

prosecution, Applicants have amended claim 74 to remove the term “intermediates”. Applicants have also amended claim 74, at steps b-c, for grammatical reasons.

Therefore, applicants respectfully maintain that the Examiner’s rejection of claim 74 and its dependent claims 75-78 on §112 grounds is now moot.

Applicants thus respectfully maintain that the Examiner’s §112 rejections have been overcome and that the above mentioned claims are in condition for allowance.

### **Rejection under §101 - Double Patenting**

The Examiner has maintained her rejection of claims 35-55 and 74-78 under 35 U.S.C. §101 as being unpatentable for double patenting over claims 35-41, 48-61 and 80-84 of U.S. Application Serial No. 10/187,498. Applicants respectfully traverse the Examiner’s rejection.

Applicants note that claims 35-41, 48-61 and 80-84 of U.S. Application Serial No. 10/187,498 were withdrawn at the time of the instant rejection. Solely to speed prosecution, applicants have submitted an amendment in U.S. Application Serial No. 10/187,498 canceling the aforementioned claims. Thus, the Examiner’s §101 rejection is moot.

### **Rejection under 35 U.S.C. §103**

The Examiner has rejected claims 49 and 102 as obvious over Torkkeli in view of Anderssen and Mourot and has rejected claim 55 as obvious over Anderssen in view of Palmer and Shin. Applicants respectfully traverse the Examiner’s §103 rejections.

Applicants note that the §103 rejection for claim 49 was previously withdrawn by the December 30, 2004 Office Action. The Examiner agreed, in the February 9, 2006 follow-up interview, that the §103 rejection of claim 49 was actually previously withdrawn by the December 30, 2004 office action and that it remains withdrawn. The Examiner further noted that

the rejection of dependent claim 102 is also withdrawn. Thus the §103 rejection of claims 49 and 102 is moot.

With respect to claim 55, the Examiner argues that “substantially free of endotoxin, nucleic acid and other contaminants” is not within the scope of the claim because substantially free of endotoxin, nucleic acid and other contaminants is not defined in the specification as meaning “pharmaceutical grade”.

Applicants respectfully point out that substantially free of endotoxin, nucleic acid and other contaminants is a property of a pharmaceutical grade compound, and therefore, that the claim term “pharmaceutical grade” is properly supported. However, solely to speed prosecution, applicants have amended claim 55 to recite “having less than 5mg/EU of endotoxin”. Support for this amendment can be found, *inter alia*, in the specification on page 29, par. 4. Applicants thus maintain that the Examiner’s §103 rejections are now moot.

### **New Rejections**

#### **Rejection for Obviousness-type Double Patenting**

The Examiner has rejected claims 101-103 for obviousness-type double patenting over claims 85-122 of U.S. Appl. No. 10/187,498. Applicants respectfully traverse the Examiner’s obviousness type-double patenting rejection.

However, applicants note that both U.S. Appl. No. 10/187,498 and this application claim priority to the same U.S. Application and thus will have the same term. In light of this, and solely to speed prosecution, applicants enclose a terminal disclaimer to U.S. Appl. No. 10/187,498 in conjunction with this response.

...

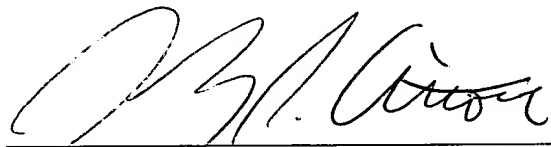
For at least the reasons set forth above, pending claims 35-55 and 74-78 are urged as being in condition for allowance. Prompt allowance is therefore respectfully requested. If

any issues remain outstanding, applicants invite the Examiner to discuss the same at a telephone interview.

No additional fees, except the fee for a three month extension of time, are believed to be necessary in connection with the filing of this Amendment. However, if any additional fees are required, the Commissioner is hereby authorized to charge such fee(s) to Deposit Account No. 50-0540.

Respectfully submitted,

Dated: March 30, 2006



Barry Evans, Reg. No. 22,802  
Henry J. Cittone, Reg. No. 57,206  
KRAMER LEVIN NAFTALIS & FRANKEL LLP  
1177 Avenue of the Americas  
New York, New York 10036  
(212) 715-9100 (telephone)  
(212 ) 715-8000 (facsimile)